

26/Declaration  
1.132

Serial No. 09/160,618



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re U.S. Patent Application

Applicant: Edwin Christensen

Serial No.: 09/160,618

Filed: September 24, 1998

For: SEMI-MOIST ORAL DELIVERY  
SYSTEM

**DECLARATION OF EDWIN CHRISTENSEN UNDER 37 CFR §1.132**

Commissioner for Patents  
Washington, D.C. 20231

I, Edwin Christensen, hereby declare as follows:

1. I am the sole inventor of the invention described and claimed in the above-identified patent application.

2. I, therefore, am familiar with the subject matter described in the above-identified application, and with the chemistry and chemical functions involved therewith.

3. Based on my knowledge and experience with such chemistry, it is my belief that the existence of sucrose in the product of the subject invention is critical to the operation of the invention.

4. If one uses a sweetener other than sucrose, such as fructose, xylose, dextrose or maltose, then the physical properties of the resulting product are changed substantially primarily because of the different crystallizing action taken by these sweeteners.

5. Such non-sucrose sweeteners do not crystallize sufficiently at the temperatures involved and thus do not sufficiently bind the product to retain a shape or

result in a product with excessive hardness or crystallize excessively so as to become too hard.

6. In the case of fructose, this sweetener is so hygroscopic as to "puddle" when used in the amounts necessary in the subject invention, that is create a pool of water when exposed to the atmosphere. As such, integrity of product and hygienic consideration dominate and mandate that it cannot be used.

7. As an example of the above-described phenomena, I conducted experiments incorporating the ingredients of the subject invention as well as substituting different sweeteners for sucrose.

8. In each experiment the ingredients were mixed and extruded as set forth in the subject application. The extruded products were cut into discrete pieces.

9. The following experiments were performed:

	Sucrose Type	Sucrose %	Starch %	Corn Syrup %	Sorbitol %	Water %	Result
1.	Sucrose	26.6	19.2	15.1	18.8	20.3	Soft, pliable, flexible, that holds its shape with a very sweet, non-gritty taste.
2.	Fructose						Tough, chewy, moderate sweetness, and a wet slippery feel-gets hard
3.	Dextrose						Rubbery, very chewy, non-sweet-eventually gets hard as rock
4.	Maltose						Slimy, very sticky, wet looking, very sweet hygroscopic
5.	Lactose						Tough, rubbery, sandy tasting, non-sweet-hard

10. When sweeteners other than sucrose were used, excessive amounts of binder were necessary to supply the binding power found by the crystallization powers

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crystallization powers of sucrose; and yet remain soft and pliable in texture.

11. Therefore I have concluded that sucrose, of the above sweeteners, is the only sweetener, which is operative in the formulation of the subject invention and achieves a lasting chewy, non-gritty texture with a sweet taste.

12. The base matrix set forth above was utilized to show the effects of substituting different "sugars" for sucrose. These tests were conducted without an active ingredient. To achieve high levels of active material the sugar level is reduced while maintaining the starch level. To increase levels of the active ingredient also require the sucrose to provide strength to the matrix while maintaining texture, mouth feel, sweetness, pliability, and non-slimey appearance, in addition to moisture control.

13. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further, these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Date: DEC. 21, 2001

Edwin Christensen  
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